



Michael R. Pence
Governor

Jerome M. Adams, MD, MPH
State Health Commissioner

DATE: November 20, 2014

TO: All Local Health Departments
Attn: Chief Food Inspection Officer

FROM: *Laurie Kidwell*
Laurie Kidwell, RRT Supervisor
Food Protection Program

SUBJECT: REFA Enterprises, LLC – RECALL [Drug]

AFFECTED PRODUCT: Forever Beautiful Bee Pollen and Forever Beautiful Infinity

SUMMARY: Unclassified Recall; The recall has been initiated because the products have been found to contain undeclared Sibutramine or a combination of both Sibutramine and Phenolphthalein. These undeclared ingredients make these products unapproved new drugs for which safety and efficacy have not been established.

All affected products are marketed as dietary supplements for weight loss and were packaged and distributed as follows:

- Forever Beautiful Bee Pollen is packaged in bottles of 60 capsules, (UPC # 6333090804632).
- Forever Beautiful Infinity is packaged in bottles of 60 capsules, (UPC # 6333090804649).

Both products were distributed via internet to consumers nationwide from July 7, 2014 – November 3, 2014.

SUGGESTED ACTION: For consumer inquiry only. Consumers with questions regarding this recall can contact REFA Enterprises, LLC at (757) 420-1122 Monday – Friday 12:00 p.m. – 6:00 p.m. EST or email support@fbbpshop.com.

Recall -- Firm Press Release

FDA posts press releases and other notices of recalls and market withdrawals from the firms involved as a service to consumers, the media, and other interested parties. FDA does not endorse either the product or the company.



2 North Meridian Street • Indianapolis, IN 46204
317.233.1325 tdd 317.233.5577
www.statehealth.in.gov

To promote and provide
essential public health services.

*REFA Enterprises, LLC Issues Voluntary Nationwide Recall of Forever
Beautiful Bee Pollen Due to Undeclared Sibutramine and
Phenolphthalein*

Contact:

Consumer:
(757) 420-1122
support@fbbpshop.com

FOR IMMEDIATE RELEASE – November 19, 2014 – REFA Enterprises, LLC is voluntarily recalling one lot of each: Forever Beautiful Bee Pollen (UPC # 6333090804632), Forever Beautiful Infinity UPC # 633090804649), to the consumer level. The products have been found to contain undeclared Sibutramine or a combination of both Sibutramine and Phenolphthalein through FDA laboratory analyses. Sibutramine is an appetite suppressant that was withdrawn from the U.S. market in October 2010 (due to increased risk of seizures, heart attacks, arrhythmia and strokes). Phenolphthalein is an ingredient previously used in over-the-counter laxatives, but because of concerns of carcinogenicity, it is not currently approved for marketing in the United States. These undeclared ingredients make these products unapproved new drugs for which safety and efficacy have not been established. Products containing sibutramine pose a threat to consumers because Sibutramine can increase blood pressure and/or pulse rate in some patients and may present a risk for those with a history of coronary artery disease, congestive heart failure, arrhythmias or stroke. These products may also interact in life threatening ways with other medications a consumer may be taking. Health risks associated with phenolphthalein could include potentially serious gastrointestinal disturbances, irregular heartbeat, and cancer with long-term use. To date, the company has not received any reports of adverse events related to this recall.

All affected products are marketed as dietary supplements for weight loss and were packaged and distributed as follows:

Forever Beautiful Bee Pollen is packaged in bottles of 60 capsules, Forever Beautiful Bee pollen was distributed via internet to consumers nationwide from July 7, 2014 – November 3, 2014.

Forever Beautiful Infinity is packaged in bottles of 60 capsules. Forever Beautiful Infinity was distributed via internet to consumers nationwide from July 7, 2014 – November 3, 2014.

REFA Enterprises, LLC is notifying its customers by email and is arranging for return of all recalled products. Consumers that have product which is being recalled should stop using and return products to REFA Enterprises, LLC.

Consumers with questions regarding this recall can contact REFA Enterprises, LLC at (757) 420-1122 Monday – Friday 12:00 p.m. – 6:00 p.m. EST or email support@fbbpshop.com.

Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using this product.

Adverse reactions experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Complete and submit the report Online: www.fda.gov/medwatch/report.htm
- Regular Mail or Fax: Download form www.fda.gov/MedWatch/getforms.htm or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

This recall is being conducted with the knowledge of the U.S. Food and Drug Administration.

REFA Enterprises, LLC Issues Voluntary Nationwide Recall of Forever Beautiful Bee Pollen Due to Undeclared Sibutramine and Phenolphthalein

Photo



